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EXAMINER	
SELLERS,R	
ART UNIT	PAPER NUMBER
1501	5

DATE MAILED: 09/12/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary	Application No. 08/603,765	Applicant(s) Assmus et al.
	Examiner Robert Sellers	Group Art Unit 1501

☒ Responsive to communication(s) filed on *Feb 20, 1996*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) *17-20* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-16* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-20* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, drawn to a coating agent comprising an acrylic plastic and a flow improver, classified in class 524, subclass 313.

II. Claims 17-20, drawn to a composition of a pharmaceutical active substance and a coating agent, classified in class 424, subclass 482.

The restriction requirement has been restructured based on the description on page 8, lines 22-26 of the specification that the acrylic plastics are derived from cationic group-containing monomers. Accordingly, claims 1-16 will be combined as well as claims 17-20 wherein the acrylic plastic with cationic groups is constructively elected.

The inventions are distinct, each from the other because:

Inventions I and II are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as an adhesive and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: The acrylic plastics with and without cationic groups and the flow improvers of claim 9.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-20 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Harris A. Pitlick on May 15, 1996 a provisional election was made with traverse to prosecute the invention of Group I, an acrylic plastic with cationic groups and a fatty acid mono, di or triglyceride as the flow improver, claims 1-16. Affirmation of this election must be made by applicant in responding to this Office action. Claims 17-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Moest.

The table in column 4 shows an example of a coating containing 37.5% by weight of an acrylic plastic with ammonium groups designated as Eudragit RS deemed to be suitable on page 13, lines 12-17.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese Patent No. 57-169427 and Nonomura et al or De Haan et al or European Application No. 204,596 and German Patent No. 4,138,513 and Moest.

The Japanese patent, Nonomura et al (col. 6, lines 26-31 and col. 4, lines 30-33), De Haan et al (col. 3, lines 64-66 and col. 4, lines 1-4 and 15-16) and the European application (according to page 3, lines 5-7 of the specification. A copy of the European application is being ordered.) disclose coating agents for pharmaceuticals comprising an Eudragit cationic group-containing acrylic plastic and fatty acid esters. The claimed amount of fatty acid ester flow improver is not recited.

The German patent sets forth a binding agent for pharmaceuticals prepared from at least 6% by weight of an Eudragit RL or RS cationic group-containing acrylic plastic (according to page 3, lines 11-16 of the specification) and from 0-30% by weight of pharmaceutical auxiliaries which includes fatty acid triglycerides based on column 2, lines 24-28 of Moest.

It would have been obvious to employ an amount of fatty acid auxiliary within the range of the German patent and Moest in order to optimize the dispersion of the Eudragit polymer in the composition.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudkin et al.

Rudkin et al is directed to a textile coating formulation comprising an Eudragit E amino group-containing acrylic plastic (col. 7, lines 9-14) and a low level of fatty acid esters and glycerides (col. 11, lines 13-24). The low levels of fatty acid esters and glycerides are within the claimed broad parameters which encompass proportions of as low as 5% by weight. It would have been obvious to employ a low level in a quantity within the claimed limits in order to optimize the conditioning of the textile.

Any inquiry concerning this communication should be directed to Robert Sellers at telephone number (703) 308-2399.

rs

9/5/96